

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

CIVIL ACTION NO. 99-20593

2:16 MD 1203

February 15, 2011

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In January, 2005, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Bassem Mikhail, M.D. Based on an echocardiogram dated December 21, 2004, Dr. Mikhail attested in Part II of Ms. Bridgewater's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.⁴ Based on

3. (...continued)

presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Mikhail also attested that claimant suffered from mild
(continued...)

such findings, claimant would be entitled to Matrix B-1,⁵
Level II benefits in the amount of \$102,405.⁶

In the report of claimant's echocardiogram, Dr. Mikhail stated that claimant had "[m]ild to moderate mitral regurgitation." Dr. Mikhail, however, did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In July, 2005, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. In

4. (...continued)
aortic regurgitation and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

5. In her Green Form, claimant requested benefits on Matrix A-1. Upon review of claimant's Green Form and supporting materials, the Trust determined, and claimant did not contest, that if eligible, Ms. Bridgewater would only receive benefits on Matrix B-1 because claimant's pharmacy records reflected Diet Drug usage of 60 days or less. See Settlement Agreement § IV.B.2.d.(2)(b).

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's findings of an abnormal left atrial dimension or a reduced ejection fraction, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

audit, Dr. Oliner concluded that there was no reasonable medical basis for Dr. Mikhail's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. He explained that "[t]here is mild [mitral regurgitation]. Estimated RJA/LAA is 10-15%. There is no [mitral regurgitation] seen in the [parasternal long-axis] view."

Based on Dr. Oliner's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Bridgewater's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷ In contest, claimant argued that under the reasonable medical basis standard, the attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant also asserted that the auditing cardiologist's determinations are inconsistent with the findings of an August 1, 2002 echocardiogram, which was performed in the Trust's Screening Program.⁸ In addition, claimant contended that "[q]uantifying the level of regurgitation shown on

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Bridgewater's claim.

8. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

an echocardiogram is inherently subjective."⁹ She further noted that there is only "a slight difference of opinion" between the auditing cardiologist and the attesting physician and that a "5% difference of opinion" as to her mitral regurgitation should not result in the denial of her claim for Matrix Benefits. Finally, claimant suggested that the Trust did not properly apply the reasonable medical basis standard established in the Settlement Agreement but rather substituted the opinion of the auditing cardiologist for that of the attesting physician.

The Trust then issued a final post-audit determination, again denying Ms. Bridgewater's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Bridgewater's claim should be paid. On January 12, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5940 (Jan. 12, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 9, 2006, and

9. In support of this assertion, claimant submitted an excerpt of a deposition of Donald L. Yakel, Jr. This testimony, however, did not address claimant's echocardiogram.

claimant submitted a sur-reply on June 30, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹⁰ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

to pay the claim in accordance with the Settlement Agreement.
See id. Rule 38(b).

In support of her claim, Ms. Bridgewater reasserts many of the arguments that she made in contest. In addition, she argues that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of mitral regurgitation and, as such, "[n]either diagnosis is correct or incorrect; both fall within the realm of having 'a reasonable medical basis.'"¹¹

In response, the Trust contends that claimant has abandoned her argument concerning the reasonable medical basis standard and that she "instead argues that the Auditing Cardiologist is somehow biased against claimants." The Trust counters that she did not present any evidence of bias. Additionally, the Trust contends that inter-reader variability does not account for the difference in findings because Dr. Oliner found that claimant's RJA/LAA ratio was at most 15%, and that there was no reasonable medical basis for Dr. Mikhail's finding of moderate mitral regurgitation. In addition, the Trust contends that a finding of "mild to moderate" mitral regurgitation cannot qualify as "moderate" even when the Green Form states that claimant had moderate mitral regurgitation if

11. In support of this argument, claimant refers to Dr. Oliner's conclusion in connection with another claim. As the issue is whether Ms. Bridgewater has established a reasonable medical basis for her claim, claimant's reliance on the auditing cardiologist's conclusion regarding a different claimant is misplaced.

the underlying echocardiogram report indicates only "mild to moderate" regurgitation. The Trust further asserts that since claimant's counsel acknowledged that claimant's RJA/LAA ratio is between 15% and 20% "[b]y definition, a point *between* two others cannot be situated on either endpoint - a ratio *between* 15% and 20% cannot be *equal* to the 'twenty percent threshold for moderate mitral regurgitation' as required by the Court." (Emphasis in original.)

In her sur-reply, claimant states that she has not abandoned any arguments concerning the reasonable medical basis standard, and that she timely raised the inter-reader variability argument during contest. In addition, she asserts that "the difference in subjective opinion between Dr. Mikhail and Dr. Oliner is very slight." According to claimant, "there is nothing contradictory in the actions of Dr. Mikhail in describing the jet as 'mild to moderate' while opining that the jet was a[t] least 20% per the Singh criteria." Further, she argues that a measurement between 15% to 20% does not mean that the regurgitant jet is less than 20% and that she need only prove that there is a reasonable medical basis for the attesting physician's representation.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Abramson explained:

In reviewing the transthoracic echocardiogram from 12/21/04, my visual estimate is that there is only mild mitral regurgitation. No [mitral regurgitation] was evident in the parasternal long axis view. I measured the mitral regurgitant jet and the left atrial area in the same frame in five representative cardiac cycles. My measurements for mitral regurgitant jet area/left atrial area are 1.06 cm²/19.19 cm², .92 cm²/19.93 cm², 1.84 cm²/19.50 cm², 1.68 cm²/19.57 cm², and 1.69 cm²/21.49 cm². These ratios are 6%, 5%, 9%, 9%, and 8%, all of which are considerably less than 20% which is consistent with mild mitral regurgitation.¹²

In response to the Technical Advisor Report, claimant argues that the Technical Advisor failed to include any visual stills or identify the exact location of her measurements of the RJA/LAA ratio. According to claimant, "without access to the actual tracings made by the Technical Advisor, the claimant can only assume the Technical Advisor over-traced the left atrial area and under-traced the regurgitant jets." She argues that the Technical Advisor may have "measured the jets too soon in the cycle, before they had reached their maximum area." Further, claimant argues that the Technical Advisor's RJA/LAA ratios of 5% to 9% are less than Dr. Oliner's RJA/LAA ratio of 10% to 15%. Thus, she contends that the Technical Advisor employed an extremely conservative measuring technique and is

12. Dr. Abramson also examined claimant's August 1, 2002 echocardiogram and found it "difficult to interpret because the machine settings are incorrectly set." Dr. Abramson concluded that she "can understand how this mitral regurgitation could have been interpreted as moderate" if it were not recognized that the settings were incorrect. In response, claimant objected to Dr. Abramson's examination of the August 1, 2002 echocardiogram since it was never at issue in this claim.

either biased against claimants or improperly trained. With respect to the Technical Advisor's statement there is no evidence of mitral regurgitation in the parasternal long-axis view, claimant contends that the Technical Advisor and Dr. Oliner admit that claimant had mitral regurgitation and, therefore, "the only conclusion that can be reached by the Technical Advisor's statement is that sometimes mitral regurgitation is present but it cannot be seen."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, she does not adequately contest Dr. Oliner's finding that Ms. Bridgewater had only mild mitral regurgitation. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Bridgewater rests only on Dr. Mikhail's check-the-box diagnosis on her Green Form and the reports of two echocardiograms. Ms. Bridgewater does not specifically refute or respond to Dr. Oliner's conclusion that her RJA/LAA ratio was between 10% and 15%. Mere disagreement with the auditing cardiologist without identifying and substantiating any specific errors by the auditing cardiologist is insufficient to meet claimant's burden of proof.

We also disagree with claimant that there is a reasonable medical basis for her attesting physician's finding of moderate mitral regurgitation because a "5% difference" is only "a slight difference of opinion." The Settlement Agreement establishes specific criteria to establish moderate mitral

regurgitation. Nothing in the Settlement Agreement allows a claimant to recover Matrix Benefits where the claimant relies on a level of mitral regurgitation that is close to the requisite level of regurgitation. To conclude otherwise would allow claimants who do not have moderate mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

Similarly, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Bridgewater had moderate mitral regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding of moderate mitral regurgitation cannot be medically reasonable where the auditing cardiologist and Technical Advisor both concluded that claimant's mitral regurgitation was mild. Specifically, Dr. Oliner estimated claimant's RJA/LAA was between 10% and 15%.¹³ In addition, Dr. Abramson measured five representative cardiac cycles and determined that claimant's

13. For this reason as well, we disagree with claimant that the conflict between the attesting physician and the auditing cardiologist is because echocardiography is "inherently subjective." Nor has Dr. Oliner merely substituted his opinion for that of the attesting physician. Instead, Dr. Oliner specifically found that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.

RJA/LAA was between 5% and 9%.¹⁴ Adopting claimant's argument on inter-reader variability would expand the range for moderate mitral regurgitation beyond the levels established by the Settlement Agreement. This result would render meaningless this critical provision of the Settlement Agreement.

Finally, we disagree with claimant's assertion that she is entitled to Matrix Benefits because an echocardiogram performed in the Trust's Screening Program demonstrated moderate mitral regurgitation. The Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive for a favorable echocardiogram performed in the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

14. Claimant's assumption that the Technical Advisor used an improper technique because she did not include visual stills or the location of her measurements is unfounded. Notably, claimant does not identify any representative frames in which the RJA/LAA ratio measures more than 20%. Similarly, we reject claimant's argument that Dr. Abramson is either biased against claimant or improperly trained simply because Dr. Abramson measured claimant's regurgitation to be between 5% and 9% while Dr. Oliner estimated claimant's regurgitation to be between 10% to 15%.

Settlement Agreement § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section § VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims for Matrix Benefits. See PTO No. 2662 at 13 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.¹⁵

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral

15. In any event, Dr. Abramson reviewed claimant's August 1, 2002 echocardiogram and determined that inappropriate machine settings "make the mitral regurgitant jet appear larger than it actually is." Other than request that references to the August 1, 2002 echocardiogram be stricken from the Technical Advisor Report, claimant does not attempt to identify any error in Dr. Abramson's analysis.

regurgitation. Therefore, we will affirm the Trust's denial of Ms. Bridgewater's claim for Matrix Benefits and the related derivative claim submitted by her spouse.